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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,597	04/09/2001	Zheng Xin Dong	00537-169002	1308

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EXAMINER	
WEGERT, SANDRA L	
ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
04/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/674,597	DONG ET AL.	
	Examiner	Art Unit	
	SANDRA WEGERT	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 52-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *11,52 and 53* is/are allowed.

6)☒ Claim(s) *54 and 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicants' request for reconsideration, filed on 6 December 2007, is acknowledged and entered. Claims 11, 52 and 53 were elected in the last Office Action; Claims 54 and 55 were withdrawn (19 September 2007).

Claims 11, 52 and 53 are allowable. The restriction requirement, as set forth in the Office action mailed on 28 August 2003 has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claims 54 and 55, directed to a method of treating a medical disorder involving the PTH2 receptor, are no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Currently, claims 11 and 52-55 are under consideration.

Withdrawn Objections and Rejections:

The rejections of claims 11, 52 and 53 for non-statutory Double-Patenting and under 35 U.S.C. 102(e) are *withdrawn* based on applicants' arguments (6 December 2007).

New Rejections:

Claim Rejections-35 *USC § 112, first paragraph - lack of enablement*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 54 and 55 are rejected under 35 U.S.C. 112, first paragraph, because the subject matter was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling for the limitations of the claims wherein a medical disorder is treated using the PTH2 analogue of SEQ ID NO: 16.

Claims 54 and 55 read on a method of treating a patient afflicted with a medical disorder that results from altered or excessive action of the PTH2 receptor. Claim 55 recites several conditions, such as: "abnormal CNS functions, abnormal pancreatic functions, divergence from

normal mineral metabolism and homeostasis, male infertility, abnormal blood pressure" and "a hypothalmic disease."

The specification discloses experiments in which muteins of a PTH2 ligand were tested in art-recognized cellular stimulation assays (Specification, p. 22, for example). In addition recent published research by the inventors shows that the variants work well in *in vitro* assays of cell function (see Chorev, et al, 2002, Biochemistry, 29: 1580-1586). The specification describes the production of several variants of the truncated PTH2 ligand, best characterized by SEQ ID NO: 16. Most experimental peptides produced by the Applicants antagonized receptor binding of competing ligands with increased specificity (compared to PTH-receptor binding) as well as affinity (Specification, p. 22 and 23).

However, the claims read on a method of treating patients for diseases related to abnormal function of the PTH2 receptor, such as CNS functions, abnormal pancreatic functions, divergence from normal mineral metabolism and homeostasis, male infertility, abnormal blood pressure and hypothalmic disease by administering the recited variants of PTH2 when, in fact, no in vivo tests were performed and no patients or animals were administered the peptides. Furthermore, there was no nexus established by the Disclosure as to the connection between the cellular data presented and the underlying mechanisms of these varied diseases. Although it is difficult to prove a negative, it seems clear that the mechanisms underlying the diseases mentioned above do not all involve the PTH2 receptor. Additionally, of course, there is the danger of *causing* disease by antagonizing the PTH2 receptor, which is found in higher concentrations in the kidneys (Usdin, T.B., 1997, Endocrinology, p. 831-833, of record, 14 May 2004).

Due to the large quantity of experimentation required to determine how to: a) use the disclosed PTH2 ligand variants to treat a medical disorder in a human or animal; b) the lack of direction or guidance in the specification regarding the same; c) the lack of working examples that administer PTH2 ligand variants to human patients or to animal models of disease; d) the state of the art which is silent as to the relationships among the PTH2 receptor and any medical disorder listed; and, e) the breadth of the claims which embrace many unrelated diseases, -- undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

Conclusion:

Claims 11, 52 and 53 are allowed. Claims 54 and 55 are rejected.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Manjunath Rao, can be reached at (571) 272-0939.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

/SLW/
29 March 2008

/Elizabeth C. Kemmerer/

Primary Examiner, Art Unit 1646